MAR 1 7 2006

K060424

Attachment 2: Special 510k Summary-Optos Panoramic 200MA

Name of Device	Panoramic 200MA Angiograph Ophthalmoscope
Common or Usual Name	Scanning laser ophthalmoscope
Classification Name	Ophthalmoscope, AC powered (per 21 C.F.R. 866.1570)
Product Code	MYC
Submitter	Optos plc, Queensferry House, Carnegie Business Campus Dunfermline, Fife, KY11 8GR United Kingdom Phone: 011 44 1383 843300 Facsimile: 011 44 1383 843333
Contact Person:	Robert Tweedlie Ph.D.
Date Prepared	8th February, 2006

Predicate Device

Trade Name	Manufacturer	510(k)
Panoramic 200A	Optos	K042001

Intended Uses

Optos plc's ("Optos") Panoramic 200MA has the same intended use and same indications as the Optos predicate device, the Panoramic 200A. Both devices are intended to examine the retina and are indicated to aid in the diagnosing and monitoring disease and disorders that manifest in the retina. Additionally, the Panoramic 200MA and Panoramic 200A are indicated for imaging the fluoresced ocular vasculature. Thus, the Panoramic 200MA Ophthalmoscope has the same intended use and same indications as the predicate device.

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Principles of Operation and Technological Characteristics

The Optos Panoramic 200MA and the predicate device are Scanning Laser Ophthalmoscopes (SLO) that work by the same method. Both devices use a laser or lasers as a light source that is scanned by a deflection system in two axes across the retina to generate an image. The returned light then travels back along the same path to a light detector that converts the light to an electrical signal. This electrical signal is digitised and used to build up an electronic picture in a computer and displayed either on a cathode ray tube or a liquid crystal display.

The above principle of operations holds for imaging the retina or a fluoresced retina. The detailed technological differences do not raise any new questions of safety or effectiveness.

Performance Standards

The Optos Panoramic 200MA Ophthalmoscope is a Class 1 laser device. This device complies with 21 C.F.R., Parts 1010 and 1040 (and also EN 60825:2001).

The Optos Panoramic 200MA Ophthalmoscope complies with the following standards:

IEC 60601-1 Second Edition 1988/A1: 1991 & A2:1995	**Medical electrical equipment. General Requirements for safety.**
EN 60601-1:1990/A1:1993, A11:1993, A12:1993 & A2:1995, A13:1996	**Medical electrical equipment. General requirements for safety.**
EN 60601-1-1:2001	**Medical electrical equipment. General Requirements for safety. Collateral Standard. Safety requirements for Medical electrical systems.**
EN 60601-1-2:2001	**Medical electrical equipment. General Requirements for safety. Collateral Standard. Electromagnetic compatibility Requirements and tests;**
EN 60601-1-4:1996	**Medical electrical equipment. General Requirements for safety. Collateral Standard. General requirements for Programmable electrical medical Systems;**
UL60601-1 First Edition:2003	**Medical electrical equipment. General requirements for safety;**
CAN/CSA-C22.2 No.601.1-M90 including S1-94	**Medical electrical equipment. General requirements for safety;**

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Conclusion

The Panoramic 200MA has the same intended use, the same indications and very similar principles of operation and technological characteristics as the predicate device. The minor technological differences between the Panoramic 200MA and the predicate devices do not raise any new questions of safety and effectiveness. Thus, the Optos Panoramic 200MA Ophthalmoscope is substantially equivalent to Optos' legally marketed Scanning Laser Ophthalmoscopes (SLO), the P200A (K042001)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2006

Optos PLC
% Hogan & Hartson, LLP
555 Thirteenth St. N.W.
Columbia Square
Washington, DC 20004
Attn: Howard M. Holstein

Re: K060424
Trade/Device Name: Panoramic, Model 200MA
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: MYC
Dated: February 17, 2006
Received: February 17, 2006

Dear Mr. Holstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Acting Division Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060424

Statement for Indication for Use

510(k) Number (if known): K060424

Device Name: Optos Panoramic ~~200A~~ 200MA Scanning Laser Ophthalmoscope

Indications for Use:

This device is indicated for use as a wide field and retinal fluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest themselves in the retina.

Prescription Use ✓ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K060424